

Workshop on Follow-On Biologics: Project No. P131208

Submission of America's Health Insurance Plans to the Federal Trade Commission on the Competitive Impacts of State Regulations and Naming Conventions Concerning Follow-on Biologic Drugs

February 27, 2014

I. Introduction

America's Health Insurance Plans (AHIP) would like to thank the Federal Trade Commission (FTC) for hosting a workshop on the Competitive Impacts of State Regulations and Naming Conventions Concerning Follow-on Biologic Drugs and for the opportunity to provide comments on these important issues. AHIP's members provide health and supplemental benefits to more than 200 million Americans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid. AHIP advocates for public policies that expand access to affordable health care coverage to all Americans through a competitive marketplace that fosters choice, quality, and innovation.

AHIP recognizes, and appreciates, the FTC's longstanding interest in promoting competition in the pharmaceutical industry. We commend the FTC for coupling its efforts to protect consumers from harmful consolidation and conduct in pharmaceutical markets with efforts to ensure that legislation and regulation does not have the unintended, and undesirable, consequence of leading to the same harms in the form of higher prices and fewer choices. In particular, AHIP notes the significance of the FTC's earlier efforts to ensure that competition between traditional, "small molecule" branded drugs and lower-priced generic alternatives was not stifled by state laws. The

FTC's input at this critical juncture helped ensure that state substitution laws were crafted or modified to avoid creating impediments to such substitution and instead to facilitate broader access to low-cost generics through avenues such as automatic substitution. The benefits to consumers from this have been well documented. Consumers have save hundreds of billions of dollars each year from the use of generics, resulting in lower costs, sustained quality, and increased access.¹

AHIP believes that we are at a critical juncture with respect to biologic pharmaceuticals.² While such biologic pharmaceuticals are both innovative and important, their costs threaten to make them unaffordable for some consumers and to raise the cost of healthcare for all. Congress recognized this problem and created a partial solution in the Biologics Price Competition and Innovation Act (BPCIA), which provides for an abbreviated regulatory pathway for the approval of follow-on biologics (FOBs) by the U.S. Food and Drug Administration (FDA).³ This

¹ See, for example, Letter of United States Government Accountability Office to Senator Orrin G. Hatch (Jan. 31, 2012)("GAO Generics Letter")(discussing cost savings from use of generic substitution, including study finding savings of \$157 billion in 2010 alone), available at: [U.S. GAO - Drug Pricing: Research on Savings from Generic Drug Use](#).

² While there are, certainly, differences between traditional generics and biosimilars, the goals of the statutes enabling an abbreviated path for their introduction are similar--allowing consumers the benefits of lower-cost alternatives that have received FDA approval. See, for example, FDA Guidance document which indicates, "The goal of the BPCI Act is similar, in concept, to that of the Drug Price Competition and Patent Term Restoration Act of 1984 (a.k.a the "Hatch-Waxman Act") which created abbreviated pathways for the approval of drug products under Federal Food, Drug, and Cosmetic Act (FFD&C Act)." FDA, Implementation of the Biologics Price Competition and Innovation Act of 2009, available at: [Guidance, Compliance & Regulatory Information > Implementation of the Biologics Price Competition and Innovation Act of 2009](#).

³ The Biologics Price Competition and Innovation Act of 2009 § 7002, 42 U.S.C. § 262, which was enacted as part of the Patient Protection and Affordable Care Act.

pathway holds tremendous promise to allow consumers increased access to biologics at lower prices, but its promise is threatened by state legislation and other developments that may stifle such FOB competition before it develops.

Therefore, we believe that the FTC's workshop and further consideration of these issues comes at exactly the right time. It is AHIP's conviction that, with further analysis and explanation of the issues by the FTC, states can ensure that any legislation or regulation developed with respect to FOBs furthers the important goal of ensuring that more patients benefit from the increased access and lower cost that they can provide. It is AHIP's further belief that, if such state statutes and regulations do hinder the development and availability of FOBs, consumers will be significantly harmed, through the loss of access to high-quality, lower-cost medications.

II. The Importance to Consumers of Developing Competition in Biologic Markets

Spending on specialty drugs such as biologics represents an increasing share of U.S. prescription drug spending and is growing at a rapid and unsustainable rate. Addressing these cost-trends is critically important to assuring a sustainable health care system and achieving affordability for businesses and consumers. Last year alone, U.S. spending on prescription drugs totaled \$263.3 billion. While specialty drugs account for only 1% of prescriptions, they represent 25% of total spending on prescription drugs.

Specialty drugs such as biologics are priced much higher than traditional drugs. While these drugs have been groundbreaking in the treatment of cancer, rheumatoid arthritis, multiple

sclerosis, and other chronic conditions, the cost of treating a patient with specialty drugs can exceed tens of thousands of dollars a year. Indeed, the treatment regimen for some of the most expensive specialty drugs can cost \$750,000 per year.

While such drugs offer tremendous promise when medically necessary, their high costs have put a strain on our health care system. The strain is borne by consumers, who must ultimately bear--directly or indirectly--the high costs of such drugs. Recognizing this, Congress attempted to provide some relief for consumers in the BPCIA. The BPCIA created an abbreviated regulatory pathway for FOBs, which would allow consumers to benefit from price competition in biologic markets following a period of exclusivity for the originator biologic. A similar pathway for follow-on generics with respect to traditional pharmaceuticals has been estimated to have saved consumers \$1 trillion dollars over a twelve year period.⁴

III. The FTC Should Continue to Assist the States and Others by Explaining the Harm to Consumers that is Likely to Follow When Regulatory and Other Impediments are Created to Follow-on Biologic Competition

A. Laws, Regulations, and Policies Should be Designed to Expand, Not Impede, the Availability of Follow-on Biologics

It is important to start with a recognition that the BPCIA was designed to make FOBs available for consumers and bring them the benefits of price competition with respect to these important medications. The statute did this by creating two categories of FOBs, both of which were contemplated as subject to FDA license and thus beneficial to consumers: (1) "biosimilars" and

⁴ See GAO Generics Letter at 10.

(2) "interchangable" biosimilars.⁵ When determining whether substitution should be facilitated (rather than impeded) at the state level, it is useful to note that Congress explicitly provided that "interchangeable" biological products "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product."⁶ Even without this explicit language, the intention of the statute to bring consumers the benefits of biosimilars and interchangeable biosimilars would be frustrated if state statutes were to make substitution available in theory but unlikely in practice.

There are a number of potential impediments to the availability of FOBs that merit the FTC's attention as an enforcement agency, competition advocate, and policy expert. For example, the FTC should renew its work on explaining that a twelve year exclusivity period for originator biologics is unnecessary to promote innovation and is likely to lead to consumer harm.

Legislative changes in this area, such the shorter exclusivity period proposed by the Administration, are likely to significantly expand access to biologics and save consumers billions of dollars. Similarly, as in traditional generic markets, the FTC should challenge any anti-

⁵ "Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if:

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c)." 42 U.S.C. § 262(k)(3).

⁶ "The term 'interchangeable' or 'interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product." 42 U.S.C. § 262(i)(3).

competitive settlements between an originator biologic company and an FOB company, and to the extent legislative changes would facilitate the FTC's work in this area, such changes should be made. Finally, other potential anti-competitive activities were raised at the workshop, such as locking-in of the first dose for patients in certain facilities. To the extent such activities violate the antitrust laws, the FTC should challenge them, and to the extent they are created or enabled by laws and regulations, the FTC should advocate for changes to those laws and regulations.

Other activities related to specialty drugs may not be specifically within the FTC's enforcement purview, but should be informed by the FTC's expert advice on the benefits to consumers from such activities. For example, CMS should be provided the flexibility to adopt a "least costly alternative" standard for certain drugs covered under Medicare Part B. The Patient-Centered Outcomes Research Institute (PCORI) should receive new authorizing language that explicitly allows it to consider research on cost-effectiveness as a valid component of patient outcomes research. Policymakers should take steps to encourage alternative payment and incentive structures, such as coverage with evidence development, for new drugs and technologies. Similarly, policymakers should pursue value-based purchasing and benefit designs in the public programs and encourage it in the private commercial sector.

Given the large and growing amount of resources devoted to specialty pharmaceuticals, no one action will be sufficient to create robust competition in these markets. Steps such as those above, and those discussed in the FTC's Workshop, however, could together provide consumers with much greater access to FOBs and other specialty pharmaceuticals at much lower costs. We would be happy to provide further information or assistance to the FTC in its efforts to promote

competition in any of the ways discussed above. Below, we provide additional information on the competitive implications of the two topics specifically identified by the FTC as subjects for comment with respect to the recent workshop.

B. State Substitution Laws

State substitution laws, such as the one adopted by North Dakota, are likely to create a meaningful barrier to the adoption and expansion of FOBs, harming consumers by reducing the availability of lower cost alternatives that provide the same quality as original biologics.⁷ North Dakota's statute includes requirements that: the pharmacist notify the prescribing practitioner within 24 hours of the substitution; the pharmacy and the prescribing practitioner retain a written record of the interchangeable biosimilar substitution for a period of no less than 5 years; the pharmacist inform the individual receiving the biological product that it may be substituted and the individual have the right to refuse the substituted product; and the Board of Pharmacy maintain on its public website a list (or a link to an FDA-approved list) of biosimilar biologic products determined to be interchangeable.⁸

Such laws generally go beyond requirements related to the substitution of a generic "small molecule" drug for a name-brand drug. By adding costs and delays to the delivery of an FOB to

⁷ State substitution laws, such as North Dakota's, are in fact misnamed, since they generally act as "impediment to substitution" laws. Substitution laws, such as those that facilitate automatic substitution of generic drugs, in contrast, are pro-consumer and would be beneficial. Our comments here focus on laws such as North Dakota's.

⁸ North Dakota S.B. 2910 - enacted, available at: [Bill Text: ND 2190 | 2013-2014 | 63rd Legislative Assembly | Enrolled | LegiScan.](#)

a consumer, such laws both raise the price to consumers of FOBs and wrongly suggest that an FOB is less valid or effective than the original biologic. If physicians, pharmacists, or consumers are dissuaded from FOBs because of such statutes, consumers will be disserved and the purpose of the BPCIA will be undermined.

In addition, such laws are likely to compound the harm of impeding the entry of existing FOBs by reducing the number of FOBs that will be created in the future. As was discussed during the FTC's workshop, FOBs involve a much more costly and time-consuming process, including more extensive FDA review, than generic pharmaceuticals. If FOB manufacturers conclude that they will not be able to effectively offer such FOBs, or only will be able to offer them effectively in certain states, they will have lower incentives to create additional FOBs. This will deny consumers the opportunity to benefit from additional lower cost, equally effective, alternatives to original biologics.

State substitution laws such as North Dakota's are premature, given that no FOBs have yet been approved by the FDA. They do not protect consumers from "lower quality" biologics, as the structure of the BPCIA and the FDA approval process ensures that FOBs are only licensed if they meet the FDA's rigorous, scientifically-driven standards and review. Finally, such laws--especially to the extent they go beyond the requirements already in place with respect to generic substitution--serve no other legitimate purpose. They do not respond to any demonstrated need for different notice, additional records, or other variations from the schemes in place for generics. In addition, as was noted at the Workshop, there are many detailed sources of information about the specific medications prescribed to, and utilized by, patients, so any

concerns about a patient's record are better addressed through improving access to such information, rather than by generating additional, unnecessary materials that serve as impediments to the entry of FOBs.

C. Naming Conventions

We agree with the FTC's conclusion that "an FOB's name can influence physician and patient acceptance of the product as a substitute for the branded biologic."⁹ Requiring different non-proprietary names for FOBs and the original biologic may impede the ability of pharmacists to substitute an FOB for a biologic and is inconsistent with the structure of naming rules, the history of such naming with respect to generics, and to the interest of consumers. It also is unnecessary to achieve any valid purpose. As noted during the FTC's workshop, there may initially be resistance among some physicians and patients to adopting FOBs, even without any artificial impediments. Past history with respect to generics suggests this as well.

In the absence of artificial impediments, though, FOBs will generate some initial acceptance and this will increase over time as knowledge about, and understanding of, FOBs increases. That is, acceptance will increase unless it is impeded by artificial impediments, such as naming rules that create the false impression that the FOB is somehow less safe or effective than the original biologic product. Such impediments will reduce the adoption of FOBs, increase costs to

⁹ Federal Register Vol. 78, No. 221 (Nov. 15, 2013) (discussing Federal Trade Commission, Emerging Health Care Issues: Follow-on Biologic Drug Competition (June 2009)).

consumers, and decrease access to these important drugs. Such impediments are also unnecessary to achieve any pro-consumer goal.

Some have suggested that changes to naming conventions are necessary to allow for more effective pharmacovigilance. The reporting of adverse events caused by pharmaceutical products is an important area of focus, and properly so. AHIP's members are supportive of improving pharmacovigilance to enhance the protection of consumers after pharmaceuticals are approved by the FDA. The issue, though, is not one of naming. As noted during the FTC's workshop, there are many existing identifiers that allow entities to distinguish pharmaceuticals by active ingredient, manufacturer, and otherwise. As was further noted, many entities are able to capture and utilize such information. If the adverse event reporting system is not sufficiently able to capture such information, the solution lies in improving the reporting process, not the naming process.

In conclusion, FOBs should have the same non-proprietary names as the original biologic product. This reflects the best execution of the intent of BPCIA to make FOBs available (and, when determined to be "interchangeable," substitutable by pharmacists), the best deference to the rigorous standards of the FDA in evaluating which FOBs should be available and substitutable, and the best interest of consumers in having FOBs available and substitutable, providing equivalent quality to original biologic products at much lower prices.

IV. Conclusion

We thank the FTC for its consideration of these important issues. AHIP believes that consumers are best served through laws and policies that support a competitive marketplace that fosters choice, quality, and innovation. The FTC's work in this area of pharmaceuticals has been significant and brought great benefit to consumers. AHIP encourages the FTC to continue these efforts, including its specific focus on follow-on biologics, coupled with its ongoing activities to ensure that state and other activities are informed by its expert voice on their potential impact.